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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,928	08/06/2003	Balaji Venkataraman	52761-0110 (286146)	1053

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EXAMINER

HENRY, MICHAEL C

ART UNIT PAPER NUMBER

1623

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/635,928

**Applicant(s)**

VENKATARAMAN, BALAJI

**Examiner**

Michael C. Henry

**Art Unit**

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-12,15-19,22-31 and 33-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-12,15-19,22-31 and 33-43 is/are rejected.
- 7) ☐ Claim(s) 35-37 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

Claims 1-5, 7-12, 15-19, 22-31, 33-43 are pending in application

#### ***Claim Objections***

Claims 35-37 are objected to because of the following informalities: The claims recite the word “folic” which appears to contain a typographical error. It appears that the word “folic” should be replaced by the word “folic acid”. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7-12, 15-19, 22-31, 33-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 1, applicant claims “a composition consisting of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6.” However, the recitation of the language “a composition consisting of” in the claim constitutes new matter as set forth in the claim. More specifically, the specification does not describe, disclose, provide or use any language or matter that pertains to any composition “consisting of” the ingredients or components recited in the claim. Furthermore, the introduction of the said new matter language “a composition consisting of” as set forth in claim 1, implies that the calcium only, and not its compounds or derivatives (such as calcium carbonate) can be used in the claimed composition.

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However, the specification refers to the calcium used in the composition as calcium carbonate (see page 3, line 4). In addition, it is well known in the art that the calcium used in these nutritional pharmaceutical compositions are in the form of a calcium compound (such as calcium carbonate, calcium sulfate, calcium oxide, calcium hydroxide, calcium apatite, calcium lactate, calcium phosphate or calcium gluconate) and not metallic calcium. Also, it should be noted that the specification describes only compositions that “comprises of” the claimed ingredients or components and not compositions that “consist of” the claimed ingredients or components. Moreover, the specification does not have support for compositions “consisting of” the claimed ingredients or components and consequently the claims contain new matter. Claims 2-43 which are drawn to the said compositions or method of use of the said compositions, are also encompassed by this rejection.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-19, 22, 24, 30, 33 and 41-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase “a condition associated with a hormonal change” in claims 15, 24 and 41-43, renders the claim indefinite. This phrase are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. More specifically, it is unclear what condition (s) are associated with a hormonal change and how must this or these condition be

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related to the hormonal change to be considered as being associated with the said hormonal change.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-12, 31, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paradissis et al. (US 5,494,678) in view of MedicineNet.com (<http://www.medicinenet.com/script/main/art.asp?articlekey=10457&page=5>, 1995, pages 1-4).

In claim 1, applicant claims "A composition consisting of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6." Claims 2-5, 7-12, 31, 34 which are further limitations of claim 1, are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and, specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3).

Paradissis et al. disclose a composition for treating pregnant women comprising calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and vitamin B1 (see abstract and claim 1).

The difference between applicant's claimed composition and the composition of Paradissis et al. is that applicant's composition does not contain vitamin B1 and contains different amount or quantity of the components and specific type of vitamin D and B12 (hydroxocobalamin).

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MedicineNet-com discloses that women in child bearing (prenant women) and adults should take one multivitamin daily. One multivitamin a day is safe and inexpensive. The multivitamin should contain 400 micrograms of folic acid, approximately 2-3 mg of vitamin B6, 6-9 micrograms of vitamin of B12, and 400 IU of vitamin D. The folic acid and the other B vitamins can help lower homocysteine. The vitamin D is one of the important factors in preventing osteoporosis. And, the amount or quantity of the components used in the composition depends on factor like the severity of the condition and the mass or age of individual being treated.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made in view of Paradissis et al. and MedicineNet.com, to prepared Paradissis et al.'s composition (for pregnant women) and to exclude vitamin B1 and use any amount or quantity of the components, since MedicineNet.com, discloses that vitamin B1 is not required in said composition, and since the amount or quantity of the components used in the composition depends on factors such as the severity of the condition and the mass or age of individual being treated.

One having ordinary skill in the art would have been motivated in view of Paradissis et al. and MedicineNet.com, to prepare Paradissis et al.'s composition (for pregnant women) and to exclude vitamin B1 and use any amount or quantity of the components, since MedicineNet.com, discloses that vitamin B1 is not required in said composition, and since the amount or quantity of the components used in the composition depends on factors such as the severity of the condition and the mass or age of individual being treated.

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***Conclusion***

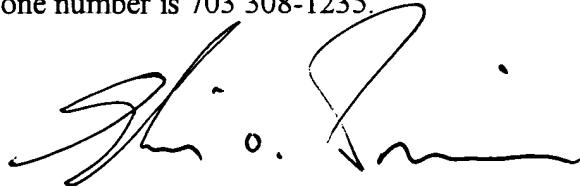
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652.

The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

June 24, 2005.



**ELVIS O. PRICE, PH.D.**  
**PRIMARY EXAMINER**